

**PLAINTIFF-RELATOR’S REPLY IN FURTHER SUPPORT OF
MOTION TO COMPEL FULL DISCLOSURE OF LEGAL ADVICE
RECEIVED REGARDING THE LAWFULNESS OF PROVIDING THE
INFUSION BUSINESS SUPPORT AND CONSULTATIVE SERVICES AT ISSUE**

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Plaintiff-Relator Julie Long filed this motion to address the significant prejudice and discovery inefficiencies that defendant Janssen Biotech has been causing by engaging in two deliberate acts in defending against Relator's claims that it violated the Anti-Kickback Statute and False Claims Act: (1) selectively revealing information showing that its attorneys not only reviewed but also subsequently *approved* of the company providing the alleged kickbacks—the infusion business support and consultative services (collectively, the “IOI Support”)—to select physicians while blocking Relator from taking discovery of the approvals, the actual underlying assessments the attorneys performed, and other legal advice Janssen received concerning whether providing the IOI Support violated the AKS; and (2) asserting an affirmative defense that it had a good faith belief that providing the IOI Support was lawful and did not violate the AKS while again blocking Relator from taking full discovery of the legal advice Janssen received that might disprove its purported belief.

In its response to this motion, Janssen has reversed course, representing that it is not and will not assert a defense that it had a good faith belief that providing the IOI Support was lawful. Accordingly, Relator's motion concerning the good faith belief defense appears now to be moot. Thus, the only issue for the Court to address is Janssen's deliberate partial disclosures that its attorneys approved of the company providing the alleged kickbacks to select physicians.

Because Janssen is trying to get away with selectively disclosing legal advice while preventing a full examination of that advice and other potentially conflicting advice, it has repeatedly claimed that it has not disclosed or relied on legal advice to defend this action. Similarly, its hyperbole that Relator is “laying trip wires” and trying to trick it into waiving the attorney-client privilege is an attempt to camouflage and distract attention from Janssen's deliberate partial disclosures and reliance on legal advice. When one looks beyond Janssen's

rhetoric and focuses on Janssen's selective disclosures and the prejudicial inferences that arise therefrom, it is clear that Janssen is improperly using the attorney-client privilege as both a sword and shield to gain an unfair advantage that could mislead the Court and factfinder into believing that Janssen did not willfully violate the AKS.

Janssen incredibly posits that its deliberate disclosure of information that could potentially refute an essential element of Relator's claim has not put that information in issue. Contrary to its assertions, Janssen has deliberately placed its attorneys' approvals of the alleged illegal conduct in issue, and they are now enmeshed in the key factual dispute of whether Janssen willfully violated the AKS. Earlier in discovery, the Court specifically instructed that Janssen could waive the attorney-client privilege if it were to use the fact that it reviewed the IOI Support with an internal committee that included an attorney in a manner that implies the attorney approved of the conduct. *See* Apr. 7, 2022 Order (ECF 303) at 4. With the benefit of a more complete record, it is now indisputable that Janssen is selectively disclosing that its attorneys approved of the company providing the alleged kickbacks to physicians. Nevertheless, Janssen continues to equivocate to try to evade or delay examination of its attorneys' decisions to approve of the company engaging in the alleged kickback scheme and other legal advice that may have warned Janssen that providing the IOI Support would be illegal.

For the reasons set forth in Relator's opening brief and this Reply, the Court should order that Janssen has impliedly waived the attorney-client privilege and must produce the assessments its attorneys conducted concerning whether providing the IOI Support violated the AKS and the advice its attorneys provided before and/or while Janssen provided the IOI Support to physicians. Alternatively, the Court should preclude Janssen from using the Promotional Review Committee approvals, preventing the attorney-client privilege from being used as both a sword and shield.

I. Because Janssen Is Partially Disclosing Legal Advice Concerning Its Attorneys' Approvals Of The Alleged Illegal Conduct, Fairness Requires Full Disclosure Of This Advice As Well As Other Legal Advice It Received On The Subject

In defending this action in which Relator must show that Janssen acted willfully in violating the AKS, Janssen has selectively disclosed that its attorneys not only *reviewed* the conduct that Relator alleges violated the AKS—providing the valuable IOI Support to targeted physician practices for free—but, more significantly, that the attorneys subsequently *approved* of the company engaging in this alleged illegal conduct. Janssen appears to be selectively disclosing this legal advice to gain an advantage in the litigation by creating the appearance that its attorneys determined and advised it that providing the IOI Support to the physician practices complied with the AKS. As part of this stratagem, Janssen is also using the attorney-client privilege to block Relator from taking discovery of the disclosed attorney approvals/determinations, including examination of the attorneys' assessments underlying these approvals and other advice the company received concerning whether providing the IOI Support would violate the AKS. In other words, Janssen has selectively disclosed legal advice it relied on when engaging in the alleged illegal conduct while withholding information about the underlying legal reviews and analyses, thereby preventing Relator from obtaining evidence that would show that the approvals were superficial, unreliable, or false, or that the attorneys did not actually assess whether the IOI Support complied with the AKS. As part of its apparent effort to get away with using the attorney approvals while depriving Relator of the ability to examine them, Janssen has gone to great lengths to create a façade that it is not disclosing or relying upon legal advice.

Earlier in the action, the Court recognized the unfairness and prejudice that would result if Janssen attempted this very maneuver and warned that if Janssen attempted to use the fact that it reviewed the IOI Support with its Promotional Review Committee (“PRC”), which included an

attorney (“PRC attorney”), in a manner that implies the attorney’s approval, it might trigger an implied waiver of the attorney-client privilege. *See* Apr. 7, 2022 Order (ECF 303) at 4. It is now clear that this is exactly what Janssen is doing. Indeed, Janssen now acknowledges that it has disclosed that its attorneys, as part of the company’s internal PRC process, approved of the company providing the IOI Support to physician practices. But yet, in an effort to continue evading discovery of these approvals that it has deliberately placed in issue and any underlying reviews that its attorneys may have conducted regarding whether the IOI Support violated the AKS, Janssen resorts to mischaracterizing the Court’s April 2022 decision, falsely asserting that other courts have permitted litigants to gain the unfair advantage Janssen is angling for, and equivocating on whether it is relying on the attorneys’ approvals.

Janssen Is Using the Attorney-Client Privilege as Both a Sword and Shield in an Attempt to Mislead the Court and Factfinder About Its Knowledge of the Unlawfulness of Its Conduct

As discovery has progressed, it has become evident that Janssen is using the attorney-client privilege as both a sword and shield to attempt to manufacture what effectively would be an irrebuttable inference that could potentially negate Relator’s allegation that Janssen acted willfully in violating the AKS. To accomplish this, Janssen has produced documents and allowed employees to provide deposition testimony evidencing four general facts¹:

- (1) Janssen reviewed the IOI Support and materials utilized in providing the IOI Support with the PRC including the PRC attorneys;
- (2) One of the purposes of the PRC reviews was for the PRC attorneys to ensure that the IOI Support complied with the law including the AKS;
- (3) The PRC attorneys approved the requests for approval to provide the IOI Support to physicians; and

¹ Submitted as Exhibit 1 to her opening brief is a spreadsheet compiling examples of evidence in the form of documents Janssen has produced, Janssen’s responses to interrogatories, and testimony Janssen has allowed concerning these four categories of asserted facts.

- (4) Employees believed they could provide the IOI Support because the PRC, including the PRC attorney, approved providing the IOI Support to physicians.

In combination, these asserted facts imply that the PRC attorneys not only reviewed whether the IOI Support violated the AKS, but, more significantly, that they concluded and advised that the IOI Support did not violate the AKS. The lynchpin of this inference is the partially disclosed legal advice that the PRC attorneys approved the requests for approval to provide the IOI Support to physicians. And so, contrary to what Janssen led the Court to believe when it was considering the prior waiver motion, Janssen is not merely providing evidence that it *reviewed* the IOI Support with its PRC; it is disclosing that, after performing those reviews, the attorneys advised the company that it could provide the IOI Support to targeted physicians. And because Janssen does not want Relator to be able to take discovery of these disclosed facts that could rebut the unsubstantiated and highly prejudicial inference it has fabricated, it is asserting the attorney-client privilege to block Relator from fully examining this legal advice and other legal advice it received regarding the same subject. *See In re von Bulow*, 828 F.2d 94, 103 (2d Cir. 1987) (“It would be unfair to allow a client to assert the attorney-client privilege and prevent disclosure of damaging communications while allowing the client to disclose other selected communications solely for self-serving purposes.” (quoting *Smith v. Alyeska Pipeline Serv. Co.*, 538 F. Supp. 977, 979 (D. Del. 1982))); *AMCA Int’l Corp. v. Phipard*, 107 F.R.D. 39, 40-44 (D. Mass. 1985) (holding plaintiff’s release of a document from its attorney waived the attorney-client privilege as to documents relating to the same subject matter).

It Is Now Clear that Janssen Has Selectively Disclosed that Its PRC Attorneys Approved the Company’s Provision of the Alleged Kickbacks to Physicians

Janssen argues that this motion should be denied because nothing has changed since the Court denied Relator’s earlier waiver motion two years ago. This is false.

When Relator asserted earlier in discovery that Janssen waived the privilege by disclosing information concerning the PRC approvals, Janssen denied that it was disclosing legal advice, arguing that its production of documents concerning the PRC review process, including PRC approval materials, should not result in a waiver because, according to Janssen, they merely show that Janssen had *reviewed* the IOI Support with the PRC including the PRC attorneys. *See* Def.’s Brf. in Opp. to Jan. 28, 2022 Mot. (ECF 272) at 6, 10-13, 15. Janssen analogized these disclosures to reporting on a privilege log that it reviewed the IOI Support with counsel. *See id.* at 12. Persuaded by Janssen’s argument, the Court ruled there was no waiver because “the PRC documents appear to show nothing more than that a lawyer *reviewed* the company’s promotional materials within the context of the company’s compliance procedures, and the documents do not appear to disclose the substance of any privileged communication.” Apr. 7, 2022 Order (ECF 303) at 2-3 (emphasis added). Significantly however, the Court instructed that if Janssen “attempt[s] to use the fact of [the PRC] *review* in a manner that implies *approval* of legal counsel, [doing so] might trigger an implied waiver.” *Id.* at 4 (emphasis added).

As plaintiff explained in her opening brief, significant discovery has taken place since the Court issued the April 2022 ruling and directives. It is now clear that, contrary to its arguments in opposing the earlier motion, Janssen has, in fact, expressly disclosed that its attorneys both *reviewed* and *approved* of the company providing the IOI Support to doctors. *See* Pl.’s Ex. 1. By selectively disclosing the PRC attorneys’ approvals, Janssen placed at issue that legal advice as well as other legal advice concerning whether providing the IOI Support violated the AKS, necessitating full disclosure of the legal advice on this critical issue. During depositions, Janssen’s employees described the attorney’s role in the PRC review process, how it was the primary way Janssen reviewed whether the IOI Support violated the AKS, *see* Pl.’s Ex.1 at pp.7-

9, and that they relied on the approvals in believing that it was permissible to provide the alleged kickbacks to physicians, *see id.* at pp.12-14. This testimony provides context to Janssen’s counsel’s earlier argument to the Court that one of the reasons Janssen believes that providing the IOI Support was lawful was because “they were reviewed and *approved* by the company’s promotional review committee.” Oct. 1, 2021 Hearing (ECF 186) at 22:2-5 (emphasis added).

Unable to continue pretending that the documents and information it has selectively disclosed do not reveal that its attorneys approved of the company providing the alleged kickbacks to physicians, Janssen now acknowledges that it has disclosed that its attorneys approved of the provision of the IOI Support. *See, e.g.*, Def.’s Brf. (ECF 430) at 8, 12.²

However, trying to evade having to turn over its attorneys’ actual reviews of the legality of the IOI Support, Janssen nonsensically asserts that its attorneys’ approvals and advice that it could engage in a strategy after purportedly reviewing whether the strategy violated the AKS do not constitute legal advice. If the PRC attorneys’ approvals were not advice, why did the company place so much reliance on them? Janssen’s assertion not only defies common sense, it is belied by the evidence Janssen has selectively disclosed concerning the PRC reviews and its employees’ testimony concerning the significance of the approvals. *See* Pl.’s Ex. 1.

Similarly, because Janssen can no longer pretend that it has not disclosed that its attorneys approved of the company providing the IOI Support, Janssen is now trying to evade discovery of the attorneys’ approvals and underlying reviews by feigning that the Court has ruled that it is permitted to disclose information concerning the PRC attorneys’ approvals while at the same time blocking Relator from taking discovery of the approvals and other legal advice

² Although Janssen refers to the documents that set forth its attorneys’ approvals of the IOI Support as “forms,” these documents reflect their actual approvals. *See, e.g.*, Pl.’s Ex. 8.

concerning whether providing the IOI Support violated the AKS. For instance, Janssen falsely asserts that when deciding Relator's earlier motion the Court held that "disclosing the fact that ... lawyers approved of a course of action in response to Relator's discovery requests does not put legal advice at issue." Def.'s Brf. (ECF 430) at 12. This is false. The Court made no such ruling and, in fact, issued a warning to Janssen stating the exact opposite: "in the future [Janssen] might attempt to use the fact of [the PRC] review in a manner that implies approval of legal counsel, which in turn might trigger an implied waiver." Apr. 7, 2022 Order (ECF 303) at 4. Moreover, Janssen's reliance on the PRC approvals is the equivalent of a covert reliance on counsel defense. The Court specifically directed that if Janssen were to assert such a defense, then privileged communications will have been placed in issue. *See id.* at 2, 4.

Janssen likewise falsely asserts that courts "have repeatedly held" that a defendant's disclosure that its attorneys approved of it engaging in the alleged illegal conduct does not place that legal advice in issue. *See* Def.'s Brf. (ECF 430) at 13. The decisions Janssen relies on do not support this meritless assertion. In *Banco do Brasil, S.A. v. 275 Washington Street Corp.*, Civ. No. 09-11343, 2011 WL 3208027 (D. Mass. July 27, 2011), a breach of contract case bearing no similarities to this case, the court held that the defendant bank did not waive the privilege by submitting an affidavit from its attorney describing actions the bank took to comply with a requirement in its lease to make a good faith effort to secure the regulatory approvals necessary to open a branch in the plaintiff's building. *See* 2011 WL 3208027, at *1, 3. Unlike here, there was no selective disclosure of legal advice, and any advice the defendant bank received was irrelevant to the plaintiff's breach of contract claim.

Janssen's reliance on *In re Intuniv Antitrust Litigation*, Civ. No. 16-12653, 2021 WL 10362709 (D. Mass. Mar. 3, 2021) is also off the mark. The issue in that case was whether a

company's disclosure of its *act* of evaluating whether to launch a drug waived the privilege. *See In re Intuniv Antitrust Litig.*, 2021 WL 10362709, at *8. The court held that "because the attorney-client privilege applies to communications, not conduct, [defendant] may introduce evidence of *actions* it took without waiving the attorney-client privilege so long as it does not present evidence of the legal advice it received before taking those actions." *Id.* at *9. Here, however, Janssen has not merely disclosed the *actions* it took, it has disclosed that its attorneys *approved* and thus advised that it could provide the IOI Support.

The assessment of whether an implied waiver is necessary is highly case-specific. Here, Janssen's disclosure that its PRC attorneys approved of the company providing the IOI Support, which, when considered with other disclosed evidence, creates an inference that the PRC attorneys reviewed whether the IOI Support violated the AKS and concluded it did not. It would be manifestly unfair and prejudicial to permit Janssen to continue playing both sides of the attorney-client privilege, allowing it to partially disclose legal advice to make unsubstantiated assertions and imply facts that could refute Relator's allegation that it acted willfully, while preventing Relator from accessing information that would enable her to test and rebut Janssen's factual assertions and the related inferences.

***The Court Should Not Wait Until Janssen More Formally Presents
Its Defenses to Address Janssen's Selective Disclosures of Legal Advice***

Janssen's contention that it should be able to block Relator from taking discovery of the PRC attorneys' approvals and other legal advice Janssen received concerning whether providing the IOI Support violated the AKS until it formally presents its defenses and uses the fact that its attorneys approved of the company providing the IOI Support to physicians to support such defenses is unjustifiable. Janssen cannot be permitted to continue obfuscating and equivocating about the defenses it is asserting. It has had ample time to determine whether it is going to use

the fact that its PRC, including the PRC attorneys, advised that it could provide the IOI Support to physician practices, and has been stating that it plans to do so.

Recognizing that a delayed assertion of a reliance upon counsel defense would cause substantial inefficiencies and delay, the Court ordered Janssen to disclose whether it is going to assert this defense. *See* Oct. 28, 2021 Order (ECF 205) and Nov. 29, 2021 Order (ECF 220). In a December 21, 2021 letter, Janssen represented that it is not asserting a reliance upon counsel defense. Janssen should not be permitted to frustrate and thwart the Court's orders by waiting until after discovery is completed to advise whether it is going to use the PRC approvals to support its defenses. Consistent with its prior order, the Court should require Janssen to advise Relator now whether it is going to use the PRC approvals.

If Janssen is going to use the PRC approvals, then Janssen must be required to make full disclosure of the attorneys' approvals and legal analyses they conducted in assessing whether providing the IOI Support would violate the AKS, including allowing Relator to depose the attorneys concerning their reviews and approvals. And because Janssen cannot selectively disclose certain legal advice while shielding other legal advice on the same subject, it must also be required to disclose the other legal advice it received concerning whether providing the IOI Support violated the AKS. *See In re Lernout & Hauspie Sec. Litig.*, 222 F.R.D. 29, 34-35 (D. Mass. 2004) (holding knowing disclosure of attorney-client privileged material waives all communications on the same subject) (citing *Texaco Puerto Rico, Inc. v. Dep't of Consumer Affairs*, 60 F.3d 867, 883 (1st Cir. 1995)); *AMCA Int'l*, 107 F.R.D. at 40-44 (holding plaintiff's release of a document from its attorney waived the attorney-client privilege as to documents relating to the same subject matter); Fed. R. Evid. 502(a).

On the other hand, if Janssen advises that it will not use or rely on the fact that its PRC,

including the PRC attorneys, approved of the company providing the IOI Support as part of any defense that it asserts, then the Court should enter an order precluding Janssen from doing so.

This would bring certainty on this important issue, allowing discovery to be more efficient.

II. Janssen Should Be Precluded From Asserting A Defense That It Had A Good Faith Belief That Providing The IOI Support Did Not Violate The Law

In responding to Relator's request that the Court rule that Janssen has impliedly waived the attorney-client privilege because it is asserting a defense that it had a good faith belief that providing the IOI Support was lawful, Janssen has reversed course, representing to the Court that it is not and will not assert this defense. *See* Def.'s Brf. (ECF 430) at 10. Janssen wrongly accuses Relator of misinterpreting Janssen's prior statements concerning whether it is asserting a good faith belief defense.³ Notwithstanding, given that Janssen has now represented that it will not assert a good faith belief defense in this action, the portion of Relator's motion related to that

³ Janssen's accusation is belied by its response to Interrogatory 20, which Relator propounded in order to specifically confirm whether Janssen was asserting a good faith belief defense after it changed its position about this defense in responding to Relator's first motion regarding waiver of the privilege two years ago. Interrogatory 20 specifically asked Janssen "whether you contend that when you provided each of the various types of IOI Support and IOI Support Program that you had a *good faith belief that your actions did not violate any law, statute, or regulation ...*" Def.'s Ans. to Pl.'s Interrog. 20 (ECF 427-2 at 36) (emphasis added). In its response, Janssen did not state that it is not asserting a good faith belief defense. To the contrary, it stated, in relevant part: "At the time the product support services were provided, and through the present, Janssen had a *good faith belief* that the services in question complied with all applicable statutory and regulatory requirements, including the requirements of the Anti-Kickback Statute and False Claims Act." *Id.* at 38 (emphasis added). Additionally, in multiple communications with Janssen's counsel concerning issues related to its defense that it had a good faith belief concerning the lawfulness of its conduct, including a motion to compel a more complete answer to Interrogatory 20, Relator again raised that Janssen was asserting a *good faith belief* defense. *See* Dec. 28, 2023 and Jan. 2, 2024 emails from Pl.'s counsel to Def.'s counsel (a copy is provided herewith as Ex. 18); Pl.'s Brf. in Supp. of Dec. 15, 2022 Mot. to Compel (ECF 346) at 5-6, 8, 10, 14, 17-18 (requesting discovery concerning Janssen's affirmative defense that it had a good faith belief that providing the IOI Support was lawful). However, Janssen never advised in its response to those communications and motion that it is not asserting a good faith belief defense. *See* Ex. 18; Def.'s Brf. in Opp. to Dec. 15, 2022 Mot. (ECF 355).

defense appears to now be moot. To bring certainty to discovery and ensure there is no further dispute regarding this defense, Relator requests that the Court place on the record that Janssen is precluded from asserting a good faith belief defense in this action.

It should be noted that, despite Janssen's contention, Relator did not file this motion for an implied waiver because Janssen is asserting a defense that it *acted in good faith* by reviewing the IOI Support with its PRC. Relator's motion clearly distinguishes between Janssen's *acted in good faith* defense and the much different *good faith belief* defense, with the motion focusing on the latter, which Janssen has now represented it is not asserting. *See* Pl.'s Brf. (ECF 427) at 16-18 (distinguishing between the *good faith belief* defense and *acted in good faith* defense).

III. CONCLUSION

For the reasons stated in Relator's opening brief in support of this motion together with the reasons set forth herein, the Court should order that Janssen has waived the attorney-client privilege with regard to the assessments concerning whether providing the IOI Support violated the AKS that its attorneys performed and the advice its attorneys provided before and/or while Janssen provided the IOI Support to physicians. Alternatively, the Court should preclude Janssen from using the approvals from the Promotional Review Committee in the litigation. In addition, the Court should order that Janssen is precluded from asserting a defense that it had a good faith belief in the lawfulness of its conduct.

Dated: February 16, 2024

Respectfully submitted,

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Certificate of Service

I hereby certify on this 16th day of February, 2024, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

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